

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Junichi MIYAZAKI et al. : Attn: BOX PCT

Serial No. NEW : Docket No. 2002\_0053A

Filed January 18, 2002

A METHOD FOR CONSTRUCTING RECOMBINANT  
ADENOVIRUS VECTOR  
[Corresponding to PCT/JP00/04815  
Filed July 18, 2000]

---

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents,  
Washington, DC 20231

Sir:

Pursuant to the provisions of 37 CFR 1.56, 1.97 and 1.98, Applicants request consideration of [X] the references listed on attached form PTO-1449 and/or [] the additional information identified below in paragraph 3. A legible copy of each reference listed on the form PTO-1449 and each U.S. patent application listed below is enclosed, except a copy is not provided for each reference previously cited by or submitted to the Patent Office in international application no. PCT/JP00/04815.

1a. [X] This Information Disclosure Statement is submitted:

within three months of the filing date (or of entry into the National Stage) of the above-entitled application, or

before the mailing of a first Office Action on the merits or the mailing of a first Office Action after the filing of an RCE,

and thus no certification and/or fee is required.

1b.  This Information Disclosure Statement is submitted  
after the events of above paragraph 1a and prior to the mailing date of a final Office Action  
or a Notice of Allowance or an action which otherwise closes prosecution in the  
application, and thus:  
(1)  the certification of paragraph 2 below is provided, **or**  
(2)  the fee of \$180.00 specified in 37 CFR 1.17(p) is enclosed.

1c.  This Information Disclosure Statement is submitted:  
after the mailing date of a final Office Action or Notice of Allowance or action which  
otherwise closes prosecution in the application, and prior to payment of the issue fee, and  
thus:  
**the certification of paragraph 2 below is provided, and**  
**the fee of \$180.00 specified in 37 CFR 1.17(p) is enclosed.**

2. It is hereby certified

- a.  that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the Statement, or
- b.  that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated in §1.56(c) more than three months prior to the filing of the Statement.

3.  Consideration of the following list of additional information (including any copending or abandoned U.S. application, prior uses and/or sales, etc.) is requested.

4. For each non-English language reference listed on the attached form PTO-1449, reference is made to:
  - a.  a full or partial English language translation submitted herewith,
  - b.  a foreign patent office search report (in the English language) submitted herewith,
  - c.  the concise explanation contained in the specification of the present application at page,
  - d.  the concise explanation set forth in the attached English language abstract,
  - e.  the concise explanation set forth below or on a separate sheet attached to the reference:
5.  A foreign patent office search report citing one or more of the references is enclosed.

Respectfully submitted,

Junichi MIYAZAKI et al.

By Warren Cheek  
Warren M. Cheek, Jr.  
Registration No. 33,367  
Attorney for Applicants

WMC/dlk  
Washington, D.C. 20006-1021  
Telephone (202) 721-8200  
Facsimile (202) 721-8250  
January 18, 2002

10/031396

JC13 Rec'd PCT/PTO 18 JAN 2002

Sheet 1 of 1

FORM PTO 1449 (modified)

ATTY DOCKET NO.  
2002\_0053ASERIAL NO.  
NEWU.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICELIST OF REFERENCES CITED BY APPLICANT(S)  
(Use several sheets if necessary)

Date Submitted to PTO: January 18, 2002

APPLICANT  
Junichi MIYAZAKI et al.FILING DATE  
January 18, 2002

GROUP

## U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA						
	AB						

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO
	AC						
	AD						

## OTHER DOCUMENT(S) (Including Author, Title, Date, Pertinent Pages, Etc.)

	AE	Journal of Virology, 71(3), March 1997, Stephen Hardy et al., "Construction of adenovirus vectors through Cre-lox recombinant", pp. 1842-1849.
	AF	Proc. Nat. Acad. Sci. USA, 93, November 1996, Frank L. Graham et al., "A helper-dependent adenovirus vector system: Removal of helper virus by Cre-mediated excision of the viral packaging signal", pp. 13565-13570.
	AG	Proc. Natl. Acad. Sci. USA, 93, February 1996, Sanae Miyake et al., "Efficient generation of recombinant adenovirus DNA-terminal protein complex and a cosmid bearing the full-length virus genome", pp. 1320-1324.
	AH	Acta Paediatrica Japonica, 38, 1996, Yumi Kanegae et al., Adenovirus vector technology: An efficient method for constructing recombinant adenovirus and on/off switching of gene expression", pp. 182-188.
	AI	Human Gene Therapy, 8(11), July 1997, Fu S, Deisseroth AB, Use of the cosmid adenoviral vector cloning system for the in vitro construction of recombinant adenoviral vectors", pp. 1321-1330.
	AJ	Gene, 166(1), December 1995, Snaith MR et al., "Multiple cloning sites carrying loxP and FRT recognition sites for the Cre and Flp site-specific recombinases", pp. 173-174.
	AK	Somatic Cell and Molecular Genetics, 22(6), 1996 Liane Chen et al., "Production and characterization of human 293 cell lines expressing the site-specific recombinase Cre", pp. 477-488.
	AL	Human Gene Therapy, 10, July 1999, Fumi Tashiro et al., "Constructing adenoviral vectors by using the circular form of the adenoviral genome cloned in a cosmid and the Cre-loxP recombination system", pp. 1845-1852.

EXAMINER

DATE CONSIDERED

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.